ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FORTEKOR PLUS 1.25 mg/2.5 mg tablets for dogs
FORTEKOR PLUS 5 mg/10 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

	pimobendan	benazepril hydrochloride
FORTEKOR PLUS 1.25 mg/2.5 mg tablets	1.25 mg	2.5 mg
FORTEKOR PLUS 5 mg/10 mg tablets	5 mg	10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Artificial special dry flavour	
Basic butylated methacrylate copolymer	
Copovidone	
Croscarmellose sodium	
Crospovidone	
Dibutyl sebacate	
Hypromellose	
Iron oxide brown (E172)	FORTEKOR PLUS 1.25 mg/2.5 mg tablets: 0.5 mg FORTEKOR PLUS 5 mg/10 mg tablets: 2 mg
Lactose monohydrate	
Magnesium stearate	
Maize starch	
Microcrystalline cellulose	
Polysorbate 80	
Povidone	
Silica, colloidal anhydrous	
Silicon dioxide anhydrous	
Sodium lauryl sulfate	
Starch pregelatinised	
Succinic acid	
Sucrose	

White and light brown oval bilayer tablets with a score line on both sides.

The tablets can be divided into equal halves.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the treatment of congestive heart failure due to atrioventricular valve insufficiency or dilated cardiomyopathy in dogs. This veterinary medicinal product is a fixed dose combination and should only be used in patients whose clinical signs are successfully controlled by administration of the same doses of the individual components (pimobendan and benazepril hydrochloride) given concurrently.

3.3 Contraindications

Do not use in cases of hypertrophic cardiomyopathies or clinical conditions where an augmentation of cardiac output is not possible for functional or anatomical reasons (e.g. aortic or pulmonary stenosis).
Do not use in cases of hypotension, hypovolaemia, hyponatremia or acute renal failure.
Do not use during pregnancy and lactation (see section 3.7).
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In cases of chronic kidney disease, it is recommended to check the dog's hydration status before starting therapy, and to monitor its plasma creatinine and blood erythrocyte counts during therapy.

As pimobendan is metabolised in the liver, the veterinary medicinal product should not be administered to dogs with severe hepatic insufficiency.

The efficacy and safety of the veterinary medicinal product has not been established in dogs below 2.5 kg body weight or under 4 months of age.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands after use.

People with known hypersensitivity to pimobendan or benazepril hydrochloride should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnant women should take special care to avoid accidental oral exposure because angiotensin converting enzyme (ACE) inhibitors have been found to affect the unborn child during pregnancy in humans.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs.

Rare (1 to 10 animals / 10,000 animals treated):	Increased heart rate[1] Diarrhoea[2], Vomiting[1,2] Anorexia[2], Lethargy[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Elevated creatinine[3] Incoordination[2] Fatigue[2]

[1] Moderate. These effects are dose-dependent and can be avoided by reducing the dose in those cases.
[2] Transient.
[3] At the start of therapy in dogs with chronic kidney disease. A moderate increase in plasma creatinine concentrations following administration of ACE inhibitors is compatible with the reduction in glomerular hypertension induced by these agents, and is therefore not necessarily a reason to stop therapy in the absence of other signs.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:
Do not use during pregnancy or lactation.

Laboratory studies in rats and rabbits with pimobendan have shown evidence of foetotoxic effects at maternotoxic doses. Laboratory studies in rats and rabbits with pimobendan have not shown any effect on fertility. Laboratory studies in rats have shown that pimobendan is excreted into milk.

Laboratory studies in rats with benazepril have shown foetotoxic effects (foetal urinary tract malformation) at maternally non-toxic doses. It is not known if benazepril is secreted into the milk of lactating bitches.

Fertility:
Do not use in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

In dogs with congestive heart failure, benazepril hydrochloride and pimobendan have been given in combination with digoxin and diuretics without demonstrable adverse interactions.

In pharmacological studies no interaction between the cardiac glycoside ouabain and pimobendan was detected. The pimobendan-induced increase in contractility of the heart is attenuated in the presence of the calcium antagonist verapamil and the ß-antagonist propranolol.

In man, the combination of angiotensin converting enzyme (ACE) inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs) can lead to reduced anti-hypertensive efficacy or impaired renal function. Therefore, the concurrent use of the veterinary medicinal product with NSAIDs or any other medications with a hypotensive effect should be considered carefully before using such combinations.

The combination of the veterinary medicinal product and other anti-hypertensive agents (e.g. calcium channel blockers, β-blockers or diuretics), anaesthetics or sedatives may lead to additive hypotensive effects. Renal function and signs of hypotension (lethargy, weakness, etc) should be monitored closely and treated as necessary.

Interactions with potassium-sparing diuretics such as spironolactone, triamterene or amiloride cannot be ruled out. It is therefore recommended to monitor plasma potassium levels when using the veterinary medicinal product in combination with a potassium sparing diuretic because of the risk of hyperkalemia.

3.9 Administration routes and dosage

Oral use.

Dose and treatment schedule:
This veterinary medicinal product is a fixed combination product which should only be used in dogs which require both active substances to be administered concomitantly at this fixed dose.

The recommended dose range for this veterinary medicinal product is 0.25–0.5 mg pimobendan per kg body weight and 0.5–1 mg benazepril hydrochloride per kg body weight divided into two daily doses. This veterinary medicinal product should be administered orally, twice daily 12 hours apart (morning and evening) and approximately 1 hour before feeding.

The tablets are breakable along the score line.

The table below may be used for guidance.

Body weight (kg) of dog	Strength and number of tablets to be administered			
	FORTEKOR PLUS 1.25 mg/2.5 mg tablets		**FORTEKOR PLUS 5 mg/10 mg tablets**	
	Morning	Evening	Morning	Evening
2.5 – 5	0.5	0.5		
5 – 10	1	1		
10 – 20			0.5	0.5
20 – 40			1	1
Over 40 kg			2	2

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose the dog should be treated symptomatically. Transient reversible hypotension may occur in accidental overdose. Therapy should consist of intravenous infusion(s) of warm isotonic saline as required.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QC09BX90

4.2 Pharmacodynamics

Benazepril hydrochloride is a prodrug which is hydrolysed *in vivo* to its active metabolite, benazeprilat. Benazeprilat is a highly potent and selective inhibitor of ACE, thus preventing the conversion of inactive angiotensin I to active angiotensin II and thereby also reducing the synthesis of aldosterone. Therefore, benazepril blocks effects mediated by angiotensin II and aldosterone, including the vasoconstriction of arteries and veins, the retention of sodium and water by the kidney, and remodelling effects (including pathological cardiac hypertrophy and degenerative renal changes). In dogs with congestive heart failure benazepril hydrochloride reduces the blood pressure and volume load on the heart. Benazepril increased the time to worsening of heart failure, and the time to death, improved clinical condition, reduced cough and improved exercise tolerance in dogs with symptomatic congestive heart failure caused by valvular disease or dilated cardiomyopathy.

Pimobendan, a benzimidazole-pyridazinone derivative, is a non-sympathomimetic, non-glycoside inotropic substance with potent vasodilating properties. It increases the calcium sensitivity of cardiac myofilaments and inhibits phosphodiesterase (type III). It also exhibits a vasodilatory action through the inhibition of phosphodiesterase type III activity.

4.3 Pharmacokinetics

Absorption
Following oral administration of pimobendan alone the absolute bioavailability of the active ingredient is 60–63%. Since this bioavailability is considerably reduced when pimobendan is administered with food or shortly thereafter, it is recommended to treat animals approximately 1 hour before feeding.

After oral administration of benazepril hydrochloride alone, the systemic bioavailability is incomplete (~13%) in dogs due to incomplete absorption (38%) and first pass metabolism. Levels of benazepril decline quickly as the drug is partially metabolised by liver enzymes to benazeprilat. There is no significant difference in the pharmacokinetics of benazeprilat when benazepril hydrochloride is administered to fed or fasted dogs.

After the oral administration of the veterinary medicinal product at twice the recommended dose to dogs, peak levels of both compounds are attained rapidly (T_{max} 0.5 h for benazepril hydrochloride and 0.85 h for pimobendan) with peak concentrations (C_{max}) for benazepril hydrochloride of 35.1 ng/ml and 16.5 ng/ml for pimobendan. Peak benazeprilat levels are seen after 1.9 h with peak concentrations (C_{max}) of 43.4 ng/ml.

Distribution
The volume of distribution at steady state is 2.6 l/kg after intravenous administration of pimobendan alone, indicating that pimobendan is distributed readily into the tissues. The mean plasma protein binding *in vitro* is 93%.

Benazeprilat concentrations decline biphasically: the initial fast phase ($t_{1/2}$ = 1.7 h) represents elimination of the free drug, while the terminal phase ($t_{1/2}$ = 19 h) reflects the release of benazeprilat that was bound to ACE, mainly in the tissues. Benazepril and benazeprilat are extensively bound to plasma proteins (85–90%), and in the tissues they are found mainly in the lung, liver and kidney.

Repeated administration of benazepril hydrochloride leads to slight bioaccumulation of benazeprilat (R = 1.47), steady state being achieved within a few days (4 days).

Metabolism
Pimobendan is oxidatively demethylated to its major active metabolite, O-desmethyl pimobendan. Further metabolic pathways are phase II, glucuronides and sulfates.

Benazepril hydrochloride is partially metabolised by liver enzymes to the active metabolite benazeprilat.

Elimination
The plasma elimination half-life of pimobendan when dosed with this veterinary medicinal product is 0.5 h, consistent with the high clearance of the compound. The main active metabolite of pimobendan is eliminated with a plasma elimination half-life of 2.6 h. Pimobendan is excreted principally in the faeces and to a lesser extent in the urine.

The plasma elimination half-life of benazepril hydrochloride and benazeprilat, when dosed with this veterinary medicinal product is 0.36 h and 8.36 h, respectively. Benazeprilat is excreted via the biliary (54%) and urinary (46%) routes in dogs. The clearance of benazeprilat is not affected in dogs with impaired renal function; therefore, no adjustment of the dose is required in dogs with renal insufficiency.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Any remaining half tablets should be discarded after 1 day.

5.3 Special precautions for storage

Store below 25 °C.

Keep the blister in the outer carton in order to protect from moisture.

Any remaining half tablet should be placed back in the opened blister and stored (for a maximum of 1 day) in the original cardboard carton.

5.4 Nature and composition of immediate packaging

The tablets are packaged in aluminium/aluminium blisters packaged into an outer cardboard box.

Pack sizes:
Cardboard box containing 30 tablets
Cardboard box containing 60 tablets

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/15/185/001 (1 x 30 tablets, 1.25 mg/2.5 mg)
EU/2/15/185/002 (1 x 60 tablets, 1.25 mg/2.5 mg)
EU/2/15/185/003 (1 x 30 tablets, 5 mg/10 mg)
EU/2/15/185/004 (1 x 60 tablets, 5 mg/10 mg)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 08/09/2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD month YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FORTEKOR PLUS 1.25 mg/2.5 mg tablets
FORTEKOR PLUS 5 mg/10 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

1.25 mg pimobendan/2.5 mg benazepril hydrochloride /tablet
5 mg pimobendan/10 mg benazepril hydrochloride /tablet

3. PACKAGE SIZE

30 tablets
60 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Keep the blister in the outer carton in order to protect from moisture.
Any remaining half tablet should be placed back in the opened blister and stored (for a maximum of 1 day) in the original cardboard carton.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

EU/2/15/185/001 (1 x 30 tablets, 1.25 mg/2.5 mg tablets)
EU/2/15/185/002 (1 x 60 tablets, 1.25 mg/2.5 mg tablets)
EU/2/15/185/003 (1 x 30 tablets, 5 mg/10 mg tablets)
EU/2/15/185/004 (1 x 60 tablets, 5 mg/10 mg tablets)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FORTEKOR PLUS

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1.25 mg/2.5 mg
5 mg/10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

FORTEKOR PLUS 1.25 mg/2.5 mg tablets for dogs
FORTEKOR PLUS 5 mg/10 mg tablets for dogs

2. Composition

Each tablet contains

Active substances:

	pimobendan	benazepril hydrochloride
FORTEKOR PLUS 1.25 mg/2.5 mg tablets	1.25 mg	2.5 mg
FORTEKOR PLUS 5 mg/10 mg tablets	5 mg	10 mg

Excipients:

	iron oxide brown (E172)
FORTEKOR PLUS 1.25 mg/2.5 mg tablets	0.5 mg
FORTEKOR PLUS 5 mg/10 mg tablets	2 mg

The tablets are bilayered, oval, white and light brown, and can be divided into halves along the score line.

3. Target species

Dogs.

4. Indications for use

For the treatment of congestive heart failure due to atrioventricular valve insufficiency or dilated cardiomyopathy in dogs. This veterinary medicinal product is a fixed dose combination and should only be used in patients whose clinical signs are successfully controlled by administration of the same doses of the individual components (pimobendan and benazepril hydrochloride) given concurrently.

5. Contraindications

Do not use in cases of cardiac output failure due to aortic or pulmonary stenosis.
Do not use in cases of hypotension (low blood pressure), hypovolemia (low blood volume), hyponatremia (low blood sodium levels) or acute renal (kidney) failure.
Do not use in pregnant or lactating dogs (see section “Special warnings ").

Do not use in cases of hypersensitivity to pimobendan, to benazepril hydrochloride or to any ingredient of the tablets.

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
In cases of chronic kidney disease, it is recommended to check the dog's hydration status before starting therapy, and to monitor plasma creatinine and blood erythrocyte counts during therapy.

As pimobendan is metabolised in the liver, the veterinary medicinal product should not be administered in dogs with severe hepatic insufficiency.

The efficacy and safety of the veterinary medicinal product has not been established in dogs below 2.5 kg body weight or under 4 months of age.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.

People with known hypersensitivity to pimobendan or benazepril hydrochloride should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnant women should take special care to avoid accidental oral exposure because angiotensin converting enzyme (ACE) inhibitors have been found to affect the unborn child during pregnancy in humans.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Do not use during pregnancy or lactation.

Fertility:
Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:
Inform the veterinary surgeon if the animal is taking, or has recently taken, any other medicines.

In dogs with congestive heart failure, benazepril hydrochloride and pimobendan have been given in combination with digoxin and diuretics without demonstrable adverse interactions.

In humans, the combination of ACE inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs) can lead to reduced anti-hypertensive efficacy or impaired kidney function. Therefore the concurrent use of this veterinary medicinal product with NSAIDs or any other medications with a hypotensive effect should be considered carefully before using such combinations.

The combination of this veterinary medicinal product and other anti-hypertensive agents (e.g. calcium channel blockers, β-blockers or diuretics), anaesthetics or sedatives may lead to additive hypotensive effects. Your veterinary surgeon may recommend to closely monitor kidney function and for signs of hypotension (lethargy, weakness etc) and treat these if necessary.

Interactions with potassium-preserving diuretics like spironolactone, triamterene or amiloride cannot be ruled out. Your veterinary surgeon may therefore recommend the monitoring of plasma potassium concentrations when using this veterinary medicinal product in combination with a potassium-sparing diuretic because of the risk of hyperkalaemia (high blood potassium).

Overdose:
In case of overdose the dog should be treated symptomatically. Transient reversible hypotension (low blood pressure) may occur in accidental overdose. Therapy should consist of intravenous infusion(s) of warm isotonic saline as required.

Major incompatibilities:
Not applicable.

7. Adverse events

Dogs.

Rare (1 to 10 animals / 10,000 animals treated):
Increased heart rate[1] Diarrhoea[2], Vomiting[1,2] Anorexia[2], Lethargy[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Elevated creatinine[3] Incoordination[2] Fatigue[2]

[1] Moderate. These effects are dose-dependent and can be avoided by reducing the dose in those cases.
[2] Transient.
[3] At the start of therapy in dogs with chronic kidney disease. A moderate increase in plasma creatinine concentrations following administration of ACE inhibitors is compatible with the reduction in glomerular hypertension induced by these agents, and is therefore not necessarily a reason to stop therapy in the absence of other signs.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use.

This veterinary medicinal product is a fixed combination product which should only be used in dogs which require both active substances to be administered concomitantly at this fixed dose.

The recommended dose range for this veterinary medicinal product is 0.25–0.5 mg pimobendan per kg body weight and 0.5–1 mg benazepril hydrochloride per kg body weight divided into two daily doses. This veterinary medicinal product should be administered orally, twice daily 12 hours apart (morning and evening) and approximately 1 hour before feeding.

The tablets are breakable along the score line.

The table below may be used for guidance.

Body weight (kg) of dog	Strength and number of tablets to be administered			
	FORTEKOR PLUS 1.25 mg/2.5 mg tablets		**FORTEKOR PLUS 5 mg/10 mg tablets**	
	Morning	Evening	Morning	Evening
2.5 – 5	0.5	0.5		
5 – 10	1	1		
10 – 20			0.5	0.5
20 – 40			1	1
Over 40 kg			2	2

9. Advice on correct administration

The tablets can be divided into halves if needed.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25 °C.
Keep the blister in the outer carton in order to protect from moisture.

Any remaining half tablet should be placed back in the opened blister and stored (for a maximum of 1 day) in the original cardboard carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or your pharmacist how to dispose of medicines no longer required.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/15/185/001 (1 x 30 tablets, 1.25 mg/2.5 mg tablets)
EU/2/15/185/002 (1 x 60 tablets, 1.25 mg/2.5 mg tablets)
EU/2/15/185/003 (1 x 30 tablets, 5 mg/10 mg tablets)
EU/2/15/185/004 (1 x 60 tablets, 5 mg/10 mg tablets)

Cardboard box containing 30 tablets
Cardboard box containing 60 tablets

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH
Heinz-Lohmann-Str. 4
27472 Cuxhaven
Germany

België/Belgique/Belgien:
PV.BEL@elancoah.com
+3233000338

Република България:
PV.BGR@elancoah.com
+48221047815

Česká republika:
PV.CZE@elancoah.com
+420228880231

Danmark:
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+3728840390

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PV.LUX@elancoah.com
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+358753252088

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+46108989397

United Kingdom (Northern Ireland):
PV.XXI@elancoah.com
+443308221732

Manufacturer responsible for batch release:
Elanco France S.A.S
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F-68330 Huningue
France